UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,203	10/27/1999	CHRISTOPHER O. OKUNJI	003/172/SAP	4366

7590 10/25/2002

ELIZABETH A. ARWINE
USAMRMC
FORT DETRICK
BUILDING 521
FREDERICK, MD 21701

EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/25/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/428,203	Okunji et al.
Examiner	**Art Unit**
Michele Flood	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 4, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above, claim(s) *13-29 and 33-35* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-12 and 30-32* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 4, 2002. Acknowledgment is made of newly submitted Claims 30-35.

Newly submitted claims 30-32 reasonably read upon the elected invention of Group III, i.e., a biologically active extract comprising an extract from at least one plant selected from the Markush group recited in Claim 1. In response to the rejection made under 35 USC 112, second paragraph, with regard to the term "extract", the Office notes that Applicant argues that the restriction made in the previous Office action of Paper No. 4 (dated October 27, 1999) to the method claims should be withdrawn, and that newly added claims drawn to a method of making a biologically extract of *Napoleonaea imperialis* be examined. However, Applicant's arguments are not persuasive because newly submitted Claims 33-35 are directed to an invention that is independent or distinct from the elected invention of Group I for the following reason: The method defined by Claims 33-35 is not drawn to a composition, but to a method of making a composition. Until the instantly claimed invention directed to a composition is deemed allowable, process claims directed to a method of making a composition will be withdrawn from further consideration but will be rejoined and fully examined for patentability as long as they are within the scope of the instantly claimed composition. Accordingly, since Applicant elected Group I (without traverse) in their response to the previous Office action, Claims 33-35 are withdrawn from consideration as being drawn to an non-elected invention.

Claims 1-12 and 30-32 are under examination.

The claims have been examined, insofar, as they read on the elected invention, namely *Napoleonaea imperialis*.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 30-32 as amended remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claim 1 are rendered uncertain by the phrase "wherein said extract is extracted using an organic solvent" because it is unclear as to what Applicant intends to direct the subject matter of the invention. As drafted, it would appear that the claim-designated extract, i.e., "A biologically active extract comprising an extract", is an extract (once obtained) which is further "extracted using an organic solvent" (for example, an extract further subjected to after-processing steps of extraction using an organic solvent). Thus, it is unclear as to the starting material of the extract comprising a plant extract which is "wherein said extract is extracted using an organic solvent". Based upon the disclosure of the instant specification, it would appear that Applicant means that the "biologically active extract" is obtained using an organic solvent? If so, it is suggested that Applicant replace the phrase, "wherein said extract is

extracted using an organic solvent", with wherein said extract is obtained using an organic solvent, so as to better define the instantly claimed invention.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11, 12 and 30 as amended remain/is rejected under 35 U.S.C. 102(b) as being anticipated by Mbah et al. (U). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant claims a biologically active extract from at least one plant selected from the group consisting of *Aframomum aulocacarpus, Aframomun danellii, Dranaena arborea, Eupatorium odoratum, Glossocalyx brevipes* and *Napoleonaea imperialis*, wherein said extract is extracted using an organic solvent. Applicant further claims a biologically active extract, wherein said extract is from *Napoleonaea imperialis*. Applicant further claims a biologically active extract, wherein said extract is from at least one of roots, stem bark, leaves, fruits or seeds

from said plant. Applicant further claims a biologically active extract as recited in claim 1 wherein said solvent is selected from a group consisting of hexane, chloroform, ethyl acetate and methanol.

Applicant argues that the Mbah fails to anticipate the claimed invention because the claimed invention is directed to extraction of *N. imperialis* for the purposes of parasitic or fungal infections. However, Applicant's argument is neither persuasive nor commensurate in scope to the limitations of the claimed invention because Mbah teaches ethanol, acetone and chloroform extracts of the leaves, stems, stem bark, roots and root bark of *Napoleonaea imperialis* which exert antimicrobial activity against bacterial species.

Thus, the cited reference is deemed to anticipate the claimed subject matter.

Claims 1, 11, 12, 30 and 31 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by Kapundu et al. (V). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1, 11, 12 and 30 was set forth above. Applicant further claims a biologically active extract as recited in claim 30, wherein said extract is methanol.

On page 615, column 2, lines 9-10, Kapundu teaches a methanolic extract obtained from the seeds of *Napoleonaea imperialis*.

The reference anticipates the claimed subject matter.

Claims 1, 11, 12 and 30-32 as amended are rejected under 35 U.S.C. 102(a) as being anticipated by Ekpendu et al. (W). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 1, 11, 12, 30 and 31 was set forth above. Applicant further claims a biologically active extract as recited in claim 30, wherein said extract is ethyl acetate.

Ekpendu teaches hexane, ethyl acetate and methanol extracts of the root bark of *Napoleonaea imperialis*.

The reference anticipates the claimed subject matter.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

October 24, 2002

CHRISTOPHER R. TATE
PRIMARY EXAMINER